

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

**A comparative study of three open ,semi-closed, and closed surgical methods in the treatment of pilonidal sinus in terms of recovery time, side effects, and costs in the: A clinical trial double blinded.**

### Protocol summary

#### Study aim

Determining the comparative study of three open, semi-closed, and closed surgical methods for the treatment of pilonidal sinus disease in terms of recovery time, complications, and costs.

#### Design

This study was designed as a double-blind randomized trial that was conducted on patients Under pilonidal sinus surgery, referring to Imam Khomeini (RA) hospital, Poldakhtar, it will be performed with 3 open, closed and semi-closed methods in 1402

#### Settings and conduct

Imam Khomeini Hospital, Poldakhtar

#### Participants/Inclusion and exclusion criteria

The entry criteria were 1- a candidate for pilonidal sinus surgery and 2- not having a history of pilonidal sinus surgery 3- not having diabetes and malignancy and the exit criteria were 1- the patient's unwillingness to cooperate, 2- the inability to communicate.

#### Intervention groups

In this study, in patients who are candidates for pilonidal sinus surgery, the intervention will be in the form of 3 methods: 1- leaving the wound open, 2- bringing the layers of the wound closer together, 3- closing the wound in the middle line.

#### Main outcome variables

Bleeding, pain, infection, recovery time, costs

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20230409057866N1**

Registration date: **2023-04-27, 1402/02/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-04-27, 1402/02/07**

Update count: **0**

#### Registration date

2023-04-27, 1402/02/07

#### Registrant information

##### Name

somayh souri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 3222 5108

##### Email address

sourisomayh88@gmail.com

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2023-04-12, 1402/01/23

#### Expected recruitment end date

2023-09-22, 1402/06/31

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A comparative study of three open ,semi-closed, and closed surgical methods in the treatment of pilonidal sinus in terms of recovery time, side effects, and costs in the: A clinical trial double blinded.

#### Public title

A comparative study of three open ,semi-closed, and closed surgical methods in the treatment of pilonidal

sinus

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Candidate for pilonidal sinus surgery No history of pilonidal sinus surgery Not having diabetes and malignancy  
**Exclusion criteria:**  
The patient's unwillingness to cooperate The patient's inability to communicate

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
Target sample size: **105**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
A table of random numbers is used for randomization. direction Using the table of random numbers first to read the numbers of the determination table Numbers will then be considered for different groups to be On one of the numbers and in one of the directions in advance Determined to move and assign numbers to different groups we give.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The study will be double blinded. Patients according to the type The intervention (each of the three methods of open, semi-closed, and closed surgery for the treatment of pilonidal sinus) is blinded, as well as the researcher who must enter the data into the checklist. The subject will be blinded to the type of intervention.

**Placebo**  
Not used

**Assignment**  
Other

**Other design features**  
In this study, there are three groups and each will receive only one different intervention and only at one time

## Secondary Ids

empty

## Ethics committees

1

**Ethics committee**  
**Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

### Street address

Shahid Fahmideh St., Hamadan

### City

hamadan

### Province

Hamadan

### Postal code

۶۵۱۷۸۳۸۷۳۶

### Approval date

2023-04-07, 1402/01/18

### Ethics committee reference number

IR.UMSHA.REC.1402.024

## Health conditions studied

1

### Description of health condition studied

Pilonidal sinus

### ICD-10 code

### ICD-10 code description

## Primary outcomes

1

### Description

Recovery time, pain, bleeding, infection, costs

### Timepoint

during the intervention until one month after the intervention

### Method of measurement

McGill questionnaire, Likert scale

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: In this study, in patients who are candidates for pilonidal sinus surgery, the intervention will be in the form of 3 methods: 1- leaving the wound open, 2- bringing the layers of the wound closer together, 3- and closing the wound in the middle line.

### Category

Treatment - Surgery

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Imam Khomeini Hospital, Poldakhtar

#### Full name of responsible person

Mohammad Hossein Ehsani  
**Street address**  
کوی بسیجیان، بیمارستان امام خمینی پلدختر  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
dr.behzad imani  
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Tawheed Square, Shahid Fahmideh St  
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+98 81 3131 0000  
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Webda@umsha.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
No  
**Title of funding source**  
Hamedan University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
empty  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
dr.behzad imani  
**Position**

Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

#### Contact

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**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to

make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Data received from participants will remain confidential but general results will be published without individual identification

**When the data will become available and for how long**

After completion of the research is accessible

**To whom data/document is available**

General

**Under which criteria data/document could be used**

It seeks to reduce the problems faced by patients with the aim of reducing complications and costs and quickly returning to work and society.

**From where data/document is obtainable**

Refer to the selected journal where the data is published to access the data

**What processes are involved for a request to access data/document**

Introduction to how to search and access valid sites and magazines

**Comments**